Draft 11/5/81

OUTLINE FOR 11/5/81 MEETING RE BARCLAY

I. Status report:

A. Brief chronology (FTC letters of 10/9 and 10/29; RJR letters of 9/29, 10/15 and 10/19).

B. Recent developments at the FTC: greater disarray than ever.

1. Miller's anti-regulatory bent, preoccupation with the budget. (Crawford: "You'll have to wait.")

2. Miller's referral to McChesney: RJR 11/2 meeting reportedly unproductive.

3. Myers to Krash (11/4):

(a) No "tar" and nicotine report until Barclay matter resolved (could be simultaneous; Myers can assure).

(b) Chairman's office has directed staff to get back to Commission as promptly as possible with supplemental memorandum concerning any changes in 10/19 staff recommendation occasioned by B&W's 10/23 submission.

(c) Myers wants no further input from the industry in the meantime; would only prolong matter; will request if he wants anything more.

(d) Staff working full-time on supplemental memo and will deal with interim action.

(e) Krash response: companies confused and uncertain as to posture of FTC, outcome; unique situation (since inception of FTC method) that 3 members of industry accuse another of cheating.

C. Possible meetings with McChesney, Crawford, Muris, Myers: seems futile, inadvisable at this juncture. (Dangers: Miller's desire to drop FTC lab; possible reopening of debate about FTC method, human smoking, etc.)

D. European initiative.

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II. Positions of various companies:

A. PM, RJR and Lorillard agree that Barclay's dilution is substantially reduced in human smoking and that the cigarette therefore "fools the machine." RJR has not given up its collapse theory (as qualified) but has expressed full support (save "protective measures") for PM position. Lorillard took issue with B&W's submission and with aspects of RJR proposal (pressure measurements), but supported PM completely.

B. L&M: leave the FTC method alone despite its limitations.

C. AB: studying the matter, but RJR proposal based on "fallacious assumption" of relationship between machine and human smoking.

D. B&W: See below. (If and when appropriate, PM can present a convincing point-by-point rebuttal.)

III. Issues:

A. FTC method.

1. B&W: (a) industry has heretofore eschewed attempts to measure results of human smoking; no way to define "average" smoker or puff (but see Kamm, PM data re reproducibility of results from a given smoker of a given product); (b) "no foundation" for PM assertion of heretofore comparable rankings whether by machine or human smoker; (c) now that competitors have raised human smoking, only B&W has produced direct evidence (retained nicotine, cotinine, carbon monoxide in exhaled breath; no recent reference to CO; see Lorillard comment, p. 5).

2. PM response: FTC method serves no purpose if it does not reflect relative rankings of products by "tar" and nicotine delivery.

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B. Dilution.

1. B&W: (a) blocking of channel exits is no different in principle than blocking ventilation holes with fingers (Kozlowski); (b) criticized PM's theory ("artificial"; no attack on PPA itself), samples (small; only PM lab employees), procedure (no masking of products), borescope film ("lips block view"), proposed labyrinth holder (staining pattern; but see p. 42); criticized RJR's pressure theory (Kamm) and its change of position to support PM; criticized Lorillard's "me too" response and "imaginative experiment" (Sloan and Curran). See B&W "butt" study ("no evidence" of reduced dilution).

2. PM response: dilution is the dispositive issue.

   (a) B&W has not favored us with Kamm's evaluation of PPM.

   (b) For "artificiality" and "discomfort", compare B&W's use of "rigid plastic sleeves" and Kamm's apparatus.

   (c) Kamm results: based on deep insertion (bulb at 8-9 mm which is usually maximum insertion, i.e., outside lip); R&D getting higher pressure readings with bulb at 4-5 mm (dental dam 2.5 times human lip pressure, Filtrona holder 4 times rather than 15 claimed by B&W).

   (d) Labyrinth holder intrudes by .5mm around perimeter of filter (human lips have similar effect). (Why was Barclay omitted?)

   (e) PM sample: Boston demo included representatives of B&W and FTC, with consistent results. (FTC can test as large a sample as it wishes.)

   (f) Unlike normal ventilated cigarettes (where smoker controls), Barclay is designed so that openings will be blocked (manufacturer controls).

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C. "Swirling smoke".

1. B&W:

(a) "Rich taste" produced by combined effect of certain "proprietary matters" and "spatial summation" phenomenon (swirling smoke contacts more surfaces of smoker's mouth, compared with thin smoke stream of Cambridge, Now, etc. which goes directly to back of mouth and is inhaled).

(b) Relies on Cain (who drew conclusions about "tar" delivery and was doing work for PM at same time).

(c) Claims it has asked for but not yet seen PM film of smoke stream patterns.

2. PM response:

(a) Film (and projector) offered through Myers weeks ago; Pepples never returned Myers' calls.

(b) Any manufacturer can produce "swirling smoke", but note marketplace performance of Doral, Multifilter.

(c) Neither Doral, Multifilter nor modified Cambridge (with baffle) shows dilution drop between mouth and machine.

(d) Lorillard: Conjecture unsupported by literature or Lorillard experience.

D. Nicotine retention.

1. B&W:

(a) Expanded study from original submission (larger sample; conducted through outside firms (no control); more products covered; "noninvasive" procedures plus machine smoking). Concedes limitations (p.31).

(b) PM approach needlessly complex and flawed (defective sample; failed to take account of puff frequency and volume, emphasizing velocity instead; formula would show 24 mg "tar" for Merit; distinction between absorption and delivery is "sophistry").

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2. PM response:

   (a) B&W obviously felt the need to do additional work.

   (b) Keys to nicotine retention analysis are filter efficiency and flow rate (velocity). Whole idea is to avoid need to consider puff frequency and volume. Puff volume is comprehended by measurement of flow rate. See B&W article.

   (c) Change in puff size or frequency will affect retained nicotine in compared products similarly; no effect on relative results.

   (d) B&W data strategically limited: no graph showing Barclay deliveries at dilution lower than 60% (p. 12 and Fig. C, TA); no mention that, by PM formula, Merit might be 24 mg "tar", but Barclay would be 26; data obviously incomplete (Fig. C) or irrelevant (Fig. B).

E. Cotinine.

1. B&W: Better index because longer half-life (30 hours) than nicotine (30 min.); reaches "plateau" after 6 half-lives. Offers Gori and Darby studies, claiming ability to distinguish differences in nicotine delivery as small as one-tenth; twice the nicotine but same "tar".

2. PM response:

   (a) Data extremely flawed: limited to ultra low tar smokers; large standard deviation (not standard error as stated).

   (b) Admits smokers will adjust patterns to maintain cotinine level.

   (c) Assumes smoker absorption of nicotine is same as FTC method delivery.

   (d) With Barclay, cotinine levels went up (increase greater than difference between FTC method deliveries, less than real difference in delivery under identical smoking conditions). (G23)

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(e) Assumes linear dose response of serum cotinine to machine nicotine yield, without any offer of proof.

(f) In theory, cotinine analysis could be done; would require stringent control (either of smoking behavior or by injections); cannot ignore physiological differences among individuals. (See Lorillard comment, p. 5; Darby & Gori - "recent advances".)

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